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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/454,252	12/02/1999	JERRY PELLETIER	248/037	3544

7590

03/12/2002

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EXAMINER

MITRA, RITA

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 03/12/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.

09/454,252

Applicant(s)

PELLETIER ET AL.

Examiner

Rita Mitra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 100-115 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 100-115 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

Status of the Claims

Applicants' amendment and response to office action dated August 15, 2001, filed on December 26, 2001 (paper #13) is acknowledged. Claims 9, 36-37, 61-64 and 93-99 have been cancelled. New claims 100-115 have been added and entered. Therefore, claims 100-115 are currently pending and are under examination.

Response to Remarks and Arguments

Withdrawal of Objections/Rejections

The objection to the specification is withdrawn in light of applicants' amendment to the specification.

Claims 9, 36-37, 61-64, 93-99 have been cancelled; therefore rejection under **35 U.S.C. 112, first paragraph** is moot.

Claims 9, 36-37, 61 and 93-96 have been cancelled; therefore rejection under **35 U.S.C. 112, first paragraph** is moot.

New Ground of Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 100-115 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specifically disclosed method for identifying a target for antibacterial agent by determining the bacterial target of one bacteriophage inhibitor protein set forth in the specification, does not reasonably provide enablement for any method for identifying any bacterial target of any bacteriophage inhibitor protein, having any structure or any variation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claim 100 and 106 are directed to a method for identifying a target for antibacterial agents, by determining a bacteriophage open reading frame product (ORF) that inhibits bacterial growth binds to a bacterial protein and identifying said bacterial protein. It is not clear what is an ORF product. Is it an RNA transcript or a translated protein product? The specification at page 11, lines 25-35 indicates that the invention provides methods for identifying a target for antibacterial agents by identifying the bacterial targets of at least one uncharacterized or untargeted inhibitor protein or RNA from a bacteriophage. However, the specification fails to describe the structure and/or function of these proteins and RNAs. Furthermore, the specification fails to describe a step of contacting ORF product with the bacterial target and no indication has been given as to how the step of identifying is accomplished. Applicants assert at page 8, lines 4-8 that identification of these inhibitor ORF is described in parent application 09/407, 804,

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however this incorporation by reference is found improper. It would require undue experimentation for a person having skill in the art to be able to practice the claimed invention because no guidance has been provided such that a person having skill in the art would know the structure with reference to the binding site of the bacteriophage inhibitor protein. There is no description given for a binding assay wherein it demonstrates the binding of a bacteriophage inhibitor protein to a bacterial target protein. The nature of the invention relates to the generation of any sequence encoding bacteriophage inhibitor protein but no indication has been made as to what activity the encoded protein must have. Claim 106 further directs to identification of a bacterial nucleic acid sequence encoding a polypeptide target of said bacteriophage inhibitor protein. It is not clear how bacterial nucleic acid is identified. No steps have been indicated as to effect the said identification. It is also not clear how does identification of nucleic acid result on identification of protein

Claim 101 is directed to a method wherein the binding is determined using affinity chromatography on a solid matrix. Specification fails to provide a specific description for the condition of the assay for the binding of bacteriophage inhibitor protein to the bacterial target protein. It is unclear how affinity chromatography as recited, "identifies a protein" without steps effecting "identification", i.e. comparison of something.

Claims 102-105 and 115 are directed to a method identifying a bacterial target protein that binds to a fragment of bacteriophage ORF product. No biological activities were attributed to the recited protein fragments and the structural information was limited. There is no disclosure about the binding activities of claimed fragments. Applicants assert on page 8, lines 3-8 that using the procedure described in the present application 6 proteins derived from phage 77 were

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identified which inhibit bacterial growth in solid and liquid assays. Identification of these inhibitor ORFs is described in the specification of the parent application 09/407804 and also in PCT Publication WO 0146383, however none of the references provides any description or demonstration of a method identifying a bacterial target protein that binds to a fragment of bacteriophage ORF product. It would require undue experimentation for a person having ordinary skill in the art to be able to practice the claimed invention because no guidance has been provided such that a person having ordinary skill in the art would know the structure with reference to the binding site of any fragment of the bacteriophage inhibitor protein. There is no description given for a binding assay wherein it demonstrates the binding of a fragment of bacteriophage inhibitor protein to a bacterial target protein. The nature of the invention relates to the generation of any sequence encoding bacteriophage inhibitor protein but no indication has been made as to what activity the encoded protein must have. Applicants' arguments on page 9 lines 6-10 have been noted but not found persuasive. Applicants assert that the "activity" of the encoded phage ORF product is described as 'an ability to inhibit bacterial growth using standard laboratory procedures.' However the specification fails to demonstrate any fragment of bacteriophage ORF product that has ability to inhibit bacterial growth. Therefore, undue experimentation would be required to make and use the claimed protein fragments.

Claim 114 is directed to a method identifying a fragment of bacterial target protein to which said bacteriophage ORF product binds. No biological activities were attributed to the recited protein fragments and the structural information was limited. Specification fails to provide a specific description for the condition of the assay for the binding of a fragment of bacterial target protein to bacteriophage inhibitor protein. There is no disclosure about the

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binding activities of claimed fragments. A partial proteolytic fragment of DnaI interacting with the 77ORF104 was demonstrated in WO 01/46383 (page 59, Example 3). However, this demonstration does not reasonably provide enablement for any method for identifying any fragment of bacterial protein, having any structure or any variation to which any bacteriophage ORF product binds.

Claims 107-113 are directed to a method of identifying a bacterial target protein that binds to a bacteriophage ORF product, wherein, said determining is performed for a plurality of bacteriophage ORF products (claims 107-111), bacterial targets (claim 112) and different bacteria (claim 113). The specification has demonstrated the ORF of bacteriophage 77 only and its expression in *Staphylococcus aureus* in Examples 1-6, pages 60-66. Several bacteriophages against pathogenic bacteria have been listed in Table 1 and at page 26 specification indicates that bacteriophage are more preferably selected from bacteriophage 77, 3A and 96, however the specification fails to describe or demonstrate the invention as claimed in claims 107-113, for example determining a bacterial target for any plurality of bacteriophage ORF products (claims 107-111); for any plurality of targets (claim 112); or any plurality of different bacteria (claim 113).

Therefore, in view of the degree of guidance given in the specification and the limited exemplification of the method using bacteriophage inhibitor protein, coupled with the unpredictability associated with sequence prediction based on activity, it would require undue experimentation for a person having ordinary skill in the art to be able to practice the claimed invention without further guidance.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 100 -114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 100 and dependent claims 101-114 are indefinite because it is not clear what is an 'open reading frame product' Is it an RNA or a protein? The phrase 'open reading frame product' renders the claim indefinite. Claims 101-114 are included in the rejection because these claims are dependent on rejected claim and does not correct the deficiency of the claim from which it depends.

Claim 102 is indefinite because of the use of the term "ORF." The term "ORF" should be preceded by the full spelled out words. Claims 103-105 are included in the rejection because these claims are dependent on rejected claim and does not correct the deficiency of the claim from which it depends.

Conclusion

Claims 100-115 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

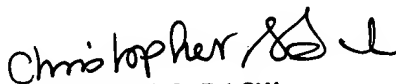
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


CHRISTOPHER S. F. LOW
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Rita Mitra, Ph.D.
March 8, 2002